

REMARKS

Reexamination and reconsideration are respectfully requested in light of the above amendments and the following remarks.

1. Status of the Claims

The status of the claims prior to amendment is as follows:

Claims pending: Claims 17-48

Claims cancelled: Claims 1-16

Claims withdrawn: Claims 32-38¹

Claims rejected: Claims 17-31 and 39-46

Claims newly introduced: Claims 47-48

Applicants note that the present claim amendments are based on the claims as of January 6, 2010.² Applicants believe that the present amendments fully comply with 37 C.F.R. § 1.121.

2. Support for the Amendments

After entry of the present amendments, Applicants (1) amend claims 17 and 39, and (2) introduce new claims 47-48 to more precisely recite the subject matter. Support for the amendment to claim 39 can be found at least from the originally filed claims. Support for the amendment to claim 17 and new claims 47-48 can be found at least in the Specification, lines 16-22, page 15, and lines 15-29, page 16. Applicants submit that no prohibited new matter is introduced by entry of the present amendments.

Cancellation of and amendments to the claims have been made without prejudice to or disclaimer of the subject matter contained therein. Applicants reserve the right to file a continuation and/or divisional on any subject matter canceled by way of amendment.

¹ The Office withdraws claims 32-38 from consideration, alleging that claims 32-38 are drawn to non-elected subject matter. Office Action mailed January 6, 2010, page 2. Applicants note that claims 32-38 are entitled to be rejoined once claims 17-31 and 39-48 are found allowable.

² The Advisory Action mailed August 4, 2010 states that the Amendment / Response filed July 2, 2010 "will be entered"... "*for purposes of appeal.*" Instead of filing an Appeal Brief, Applicants file the Amendment / Response with an RCE.

3. **Priority**

Applicants appreciate the Office's acknowledgement on page 2 of the Advisory Action mailed August 4, 2010 that the certified priority documents have been received.

4. **Drawings**

Applicants appreciate the Office's acknowledgement on page 2 of the Advisory Action mailed August 4, 2010 that the drawings filed January 23, 2006 have been entered.

5. **Information Disclosure Statement**

Applicants respectfully request with the Office's next official communication that the Information Disclosure Statement submitted August 3, 2010, be acknowledged and returned.

6. **Summary of Telephonic Interview**

Applicants appreciate the telephonic interview conducted on August 17, 2010 between Examiner Ardin Marschel and Applicants' representatives. During the interview, the basis for the rejection under 35 U.S.C. § 103(a) was discussed. Examiner Marschel indicated that the Amendment / Response filed July 2, 2010 is sufficient to overcome the rejection under 35 U.S.C. § 112, second paragraph.

7. **Withdrawn Rejections**

Rejections and objections not reiterated are withdrawn. *See* 37 C.F.R. § 1.113(b); M.P.E.P. §§ 706.07 and 707.07(e).

8. **Rejection of the Claims Under 35 U.S.C. § 112, Second Paragraph**

The Office rejects claims 39-46 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Applicants amend claim 39 to recite "a method of preparing a food or drink having an effect of ameliorating liver diseases associated with hepatopathy." The Office's rejection is thus moot. Applicants respectfully request withdrawal of the rejection, and allowance of the

claims. *See also* Interview Summary mailed August 23, 2010 (“the rejection of record under 112, 2nd paragraph, has been overcome via claim amendment filed 7/2/2010.”).

9. Rejection of the Claims Under 35 U.S.C. § 103(a)

The Office maintains the rejection of claims 17-31 and 39-46 under 35 U.S.C. § 103(a) as allegedly obvious over **Bistran** et al., U.S. Patent No. 5,320,846 (“Bistran”) and **Akimoto** et al., U.S. Published Application No. 2004/0171127 (“Akimoto”).

Bistran allegedly teaches administering a total enteral nutritional diet or a dietary supplement to treat patients with clinical disorders. Office Action mailed January 6, 2010, page 4. The patient allegedly may suffer from cancer, a clinical liver dysfunction or trauma such as ischemia, trauma, sepsis, malnutrition, liver surgery, hepatitis, or liver transplant. *Id.* The diet allegedly consists essentially of a lipid source, a protein source, a vitamin source, a carbohydrate source, and a mineral source. The lipid source allegedly contains essential fatty acids such as omega-9 fatty acid. *Id.* Akimoto allegedly teaches preparing a fat comprising a triglyceride with an omega-9 fatty acid moiety. *Id.*, at 4-5. The fat allegedly may be used in foods and pharmaceuticals for treating and preventing arteriosclerosis, thrombosis, and cancer. *Id.*, at 5.

The Office argues that it would have been obvious to combine the teachings of Bistran and Akimoto to produce a method of ameliorating liver diseases by administering an omega-9 unsaturated fatty acid. *Id.* The Office further relies on *In re Kerkhoven*, 626 F.2d 846, 850, 205 U.S.P.Q. 1069, 1072 (C.C.P.A. 1980) (“It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the same purpose.”). Office Action, page 5. The same purpose allegedly refers to (1) the hepatitis-treating effect by the Bistran’s composition, and (2) the anti-inflammatory function of omega-9 fatty acids according to Akimoto. *Id.*, at 8-9. The Office alleges, “[h]epatitis is an inflammation of the liver, therefore, to a patient to be treated for hepatitis is in need of an anti-inflammatory drug.” *Id.*, at 9.

Applicants traverse the rejection to the extent it applies to the amended claims. The traverse is on the following grounds.

9.1. The cited references fail to teach all claim elements

“[O]bviousness requires a suggestion of *all* limitations in a claim.” *CFMT, Inc. v. Yieldup Int’l Corp.*, 349 F.3d 1333, 1342, 68 U.S.P.Q.2d 1940, 1947 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985, 180 U.S.P.Q. 580, 583 (C.C.P.A. 1974) (emphasis added). Obviousness cannot be proven merely by showing that a known component or method could have been modified by routine experimentation. The Office must provide evidence that a skilled artisan would have had some *apparent reason* to modify a known component or method in a way that would result in the claimed composition or method. *See e.g. Ex parte Whalen*, 89 U.S.P.Q.2d 1078, 1084 (Bd. Pat. App. & Int. 2008) (precedential).

Amended claim 17 recites, *inter alia*, (1) “administering an omega-9 unsaturated fatty acid or a compound having an omega-9 unsaturated fatty acid as a constituent fatty acid *as an active component ... to ameliorate liver diseases associated with hepatopathy*”; and administering “the active component, in terms of omega-9 unsaturated fatty acid, *in an amount of* (1) 0.001-10 g per day, or (2) 0.001-20 g per 60 kg body weight in 1-3 divided doses daily.” Neither reference teaches at least these elements.

Bistran teaches a treatment for clinical disorders characterized by depletion of metabolic energy sources. *See e.g.*, Abstract of Bistran. Bistran states, for example:

There remains a need for an improved method of increasing energy levels of splanchnic tissue. Especially in transplant situations, organs have depleted energy stores and cannot de novo produce required metabolic energy.

Accordingly, it is an object of the invention to provide an improved method for increasing ATP levels in patients suffering from a form of splanchnic disorder.

...

The present invention generally relates to *providing adenosine, or one of its related nucleosides*, in an enteral feeding regimen which enables splanchnic tissues to more rapidly generate ATP, or other related nucleotides, during or following shock or trauma, including post-transplant situations.

See Bistran, col. 2, lines 35-42; col. 3, lines 63-68 (emphasis added). Additionally, Bistran describes the “*effective*” component of the diet as adenosine. Bistran summarizes the invention as set forth below:

The invention includes a total enteral nutrition diet having nutritionally *acceptable amounts* of a lipid source, a protein source, a carbohydrate source, a

vitamin source, and a mineral source, and an *effective amount* of adenosine to achieve normal metabolic levels of ATP and/or its precursors in ATP deficient organs of a recipient host.

Abstract of Bistrian (emphasis added). Bistrian's lipid component (including omega-9 fatty acids) is merely supplemented as a general nutrition ingredient—as other ingredient in the total enteral nutrient diet: the protein source, the carbohydrate source, the vitamin source, and the mineral source, none of these ingredients functions to treat liver dysfunctions.

Furthermore, a skilled artisan, in view of Bistrian, would not have had an *apparent reason* to include or modify the amount of the omega-9 fatty acids in the total enteral nutrient diet to a level within the presently claimed ranges. A skilled artisan, following Bistrian's teachings, would have provided only as much omega-9 fat acid as is “adequate” for a total enteral nutrition diet. In fact, omega-9 fatty acid is *not required*, if the intake of omega-3 or omega-6 fatty acid is sufficient:

Omega-9

Omega-9 is a nonessential fatty acid, since it is produced naturally by the body. It does not need to be supplemented. Omega-9 is mainly used when there is an insufficiency of either omega-3, omega-6 or both. When the body doesn't have enough omega-3 or omega-6, it tries to compensate by producing omega-9 fatty acids to take their place. Omega-9 derivatives aren't as effective as omega-3 or omega-6 though and our health will eventually suffer.³

There would have been no motivation at the time for a skilled artisan to supplement the lipid source of Bistrian with omega-9 fatty acid, because it would have been considered unnecessary, if the uptake of adequate omega-3 or 6 fatty acid is adequate. Bistrian's “vegetable oil, fish oil or combinations” would have been expected to provide sufficient nutritional levels of the essential fatty acids (omega-3 fatty acids, omega-6 fatty acids, or a combination thereof), thereby obviating the need for supplementing any omega-9 fatty acid.

Accordingly, Bistrian fails to suggest omega-9 polyunsaturated fatty acids as the active ingredient to ameliorate liver diseases, let alone the amount of omega-9 polyunsaturated fatty acids to be administered to ameliorate liver diseases.

³ See W. Embar, “Nutrition Information – Omega-3, 6 and 9,” *available at* http://www.veganpeace.com/nutrient_information/nutrient_info/omega_info.htm#Omega-9 (Copyright © 2005-2009) (enclosed as **EXHIBIT 1**).

The secondary reference, Akimoto, fails to cure at least the above defects of Bistran. Akimoto is directed to a production method for “an oil containing triglyceride in which medium chain fatty acids are bound to the 1- and 3-positions of the triglyceride and polyunsaturated fatty acid is bound to the 2 position.” *See* Akimoto, Abstract. Akimoto does not suggest any specific medical or therapeutic effect(s) of the resulting triglyceride or triglyceride-containing oil. Akimoto merely teaches the following:

- 1) omega-3 fatty acids “have numerous physiological functions such as preventative effects on adult disease such as arteriosclerosis and thrombosis, an anticancer action and an action that enhances learning acquisition”;
- 2) the omega-6 fatty acid dihomo- γ -linolenic acid “is expected to demonstrate precursor effects on type I prostaglandins, antithrombotic action, blood pressure lowering action, antidyskinetic action, anti-inflammatory action, delayed allergy inhibitory effects, skin protective action and anticancer action;” and
- 3) omega-9 fatty acids “are able to become precursors of the leucotriene 3 group in the body, and their physiological activity is the target of considerable expectation and reported examples of which include anti-inflammatory, antiallergic and anti-rheumatic action.”

See id., ¶¶ [0004] and [0014]-[0015]. Akimoto does not suggest using an omega-9 fatty acid or an omega-9-constituted fat as the **active component** to ameliorate liver diseases associated with hepatopathy, let alone administering omega-9 polyunsaturated fatty acids in the presently claimed amount. Accordingly, Bistran and Akimoto, alone or when viewed in combination, fail to teach or suggest all claim elements. Without all claim elements taught, there can be no expectation that the presently claimed methods would have worked predictably.

9.2. The Office’s rationale to combine the cited references is unsupported.

The references of Bistran and Akimoto are directed to different objectives. Bistran teaches using adenosine or related nucleotides (but not an omega-9 fatty acid or an omega-9-constituted fat) as **the active component** to treat various splanchnic disorders. Akimoto teaches that omega-9 fatty acids are metabolized to leucotrienes to exert the anti-inflammatory, anti-

allergic, and anti-rheumatic actions. *See e.g.*, Akimoto, ¶ [0015].⁴ A skilled artisan would not have been motivated to combine Bistrian and Akimoto, let alone that the combination could have been used to ameliorate liver diseases associated with hepatopathy by administering “an omega-9 unsaturated fatty acid or a compound having an omega-9 unsaturated fatty acid as a constituent fatty acid *as an active component*,” let alone in the presently claimed amount.

The Office’s reliance upon *Kerkhoven* is unsupported given the above arguments. The Bistrian’s composition and the oil composition of Akimoto do *not* serve a common purpose. Nor do they share the same active component(s). Accordingly, *Kerkhoven* does not apply.

In summary, claims 17-31 and new claims 47-48 are nonobvious over cited references. Claims 39-46 are similarly non-obvious for reciting using an omega-9 fatty acid or an omega-9-constituted fat as an active component to ameliorate liver diseases. Accordingly, Applicants respectfully request withdrawal of the obviousness rejection and allowance of claims 17-31 and 39-46.

⁴ “[0015] Fatty acids of ω9 series polyunsaturated fatty acids such as 5,8,11-eicosatrienoic acid (20:3 ω9 series, to be referred to as Mead acid) and 8,11-eicosadienoic acid (20:2 ω9 series) are known to be present as one of the constituent fatty acids in animal tissue deficient in essential fatty acids. However, since they are only present in minute amounts, their isolation and purification has been extremely difficult. *These polyunsaturated fatty acids are able to become precursors of the leucotriene 3 group in the body, and their physiological activity is the target of considerable expectation and reported examples of which include anti-inflammatory, antiallergic and anti-rheumatic action* (Japanese Unexamined Patent Publication No. 7-41421). Thus, although there is similarly a need for the development of triglycerides in which medium-chain fatty acids are bound to the 1,3-positions and ω9 series polyunsaturated fatty acid is bound to the 2-position, the existence of oils and fats (triglycerides) having a high content of ω9 series polyunsaturated fatty acid is unknown, and there are no known findings whatsoever relating to the production of a triglyceride for that purpose.” (emphasis added).

CONCLUSION

The application is believed to be in condition for allowance. Should the Office have any questions or comments regarding Applicants' amendments or response, the Office is requested to contact Applicants' undersigned representative. Please direct all correspondence to the below-listed address.

In the event that the Office believes that there are fees outstanding in the above-referenced matter and for purposes of maintaining pendency of the application, the Office is authorized to charge the outstanding fees to Deposit Account No. 50-0573. The Office is likewise authorized to credit any overpayment to the same Deposit Account Number.

Respectfully Submitted,

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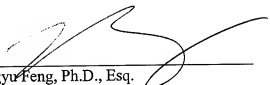

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EXHIBIT I

W. Embar, "Nutrition Information – Omega-3, 6 and 9," (*available at* http://www.veganpeace.com/nutrient_information/nutrient_info/omega_info.htm#Omega-9 (Copyright © 2005-2009)).



Vegan Peace Home

Omega-3, 6 and 9

Omega-3 and Omega-6/Good Omega-3 Sources/Omega-9

Introduction

Vegan Food Pyramid

Food Dictionary

- Definitions
- Pictures

Nutrient Information

- Macronutrients
- Vitamins
- Minerals
- Fatty Acids
- Omega-3, 6 and 9
- Good Sources

Nutrient Content Tables

- Introduction
- Categories

Daily Values

DRIs

- Definition DRIs
- Energy
- Macronutrients
- Vitamins
- Minerals

Resources

Omega-3 and Omega-6

Two important polyunsaturated fatty acids are linoleic acid and alpha-linolenic acid. Linoleic acid is used to build omega-6 fatty acids and alpha-linolenic acid is used to build omega-3 fatty acids. These fatty acids cannot be synthesized in the body and must be supplied by the diet. They are called essential fatty acids. Omega-3 and omega-6 fatty acids are important in the normal functioning of all tissues of the body. You should make sure you include good sources of omega-3 and omega-6 each day.

Pregnant women have an increased need for omega-3 and omega-6 fatty acids. They are needed for the fetal growth, brain development, learning and behavior. Lactating women should also increase their fatty acids intake, since infants receive their essential fatty acids through the breast milk.

Omega-6 fatty acids can be found in leafy vegetables, seeds, nuts, grains and vegetable oils (corn, safflower, soybean, cottonseed, sesame, sunflower). Most diets provide adequate amounts of omega-6. Unless you eat a diet that is extremely low in fat, it is very easy to get more than enough omega-6. Supplementation of omega-6 is usually not necessary.

Omega-3 fatty acids can be found in far less foods than omega-6 fatty acids. Many people have a very low intake of omega-3s. Since omega-6 fatty acids compete with omega-3 fatty acids for use in the body, it is important to take these fatty acids in the proper ratio. The World Health Organization recommends a ratio of 5:1 to 10:1 omega-6 to omega-3. While a ratio between 1:1 and 4:1 is often considered as being optimal. Since most diets are very rich in omega-6 and low in omega-3, the ratio is often somewhere between 10:1 and 20:1. This is especially a problem with diets that are high in processed foods and oils. Oils like corn, safflower, sunflower and cottonseed are usually low in omega-3s. To balance the fatty acids out, it is important to eat a diet that is low in processed foods and with fat mainly coming from omega-3 fatty acids.

Many people have a deficiency of omega-3 without realizing it, since the symptoms can often be attributed to other health conditions or nutrient deficiencies. Symptoms of an omega-3 deficiency include fatigue, dry and/or itchy skin, brittle hair and nails, constipation, depression, frequent colds, poor concentration, lack of physical endurance and joint pain.

Good Omega-3 sources

- ground flaxseed
- oils (like flaxseed oil, linseed oil, canola oil, walnut oil, wheat germ oil and soybean oil)

- green leafy vegetables (like lettuce, broccoli, kale, spinach and purslane)
- legumes (like mungo, kidney, navy, pinto, lima beans, peas and split peas)
- citrus fruits, melons, cherries

Omega-3s are damaged by heat, so the oils should not be cooked with. They are also damaged by oxidation; that's why you should store the oils in dark bottles in the refrigerator or freezer.

The absolute best source of omega-3 are flaxseeds. One tablespoon of ground flaxseed will supply the daily requirement of omega-3. Flaxseeds need to be ground for your body to be able to absorb the omega-3 from them. You can grind flaxseeds in a spice grinder. Once flaxseeds are ground, the shells don't protect them from oxidation anymore and you will need to store them in the refrigerator or freezer, just like the oils.

Omega-9

Omega-9 is a family of fatty acids which includes two major fatty acids called stearic acid and oleic acid. Stearic acid is a saturated fat which can be converted to oleic acid, which is monounsaturated. Oleic acid is the most abundant fatty acid found in nature and the primary oil produced by skin glands.

Omega-9 is a nonessential fatty acid, since it is produced naturally by the body. It does not need to be supplemented. Omega-9 is mainly used when there is an insufficiency of either omega-3, omega-6 or both. When the body doesn't have enough omega-3 or omega-6, it tries to compensate by producing omega-9 fatty acids to take their place. Omega-9 derivatives aren't as effective as omega-3 or omega-6 though and our health will eventually suffer.